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March 29, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. 98D-1266 -- Draft Guidance for Industry on Placing the Therapeutic Equivalence code on Prescription Drug Labels and Labeling

To Whom It May Concern:

The American Society of Health-System Pharmacists (ASHP) is pleased to provide comments to the FDA on the January 28, 1999, *Federal Register* notice and request for comments on the agency's draft guidance on placing therapeutic equivalence codes on prescription drug labels and labeling. ASHP is the 30,000-member national professional association that represents pharmacists who practice in hospitals, health maintenance organizations, long-term care facilities, home care agencies, and other components of health care systems.

ASHP agrees with the FDA that there is a need to better inform health professionals about whether a specific drug product is therapeutically equivalent to another pharmaceutically equivalent drug product. ASHP's "Guidelines on Formulary System Management," states our position that "the use of therapeutically equivalent products can contribute to improvement in the drug use process by maintaining a high quality of drug therapy in the most cost-effective manner." The more information that is available will allow, as the guidance document states, "pharmacists and other health professionals who practice drug product selection for patients ... [to] become more knowledgeable about which product may be safely substituted for another."

ASHP believes that the issuance of the draft guidance is particularly timely in light of recent attempts to convince various state legislatures to enact legislation obstructing generic substitution of therapeutically-equivalent narrow therapeutic index (NTI) drugs. ASHP has provided information to interested parties in this debate reaffirming and commending the FDA's efforts to clear up the misperceptions surrounding the interchange of therapeutically equivalent drugs. Therefore, the specific statement in the guidance document that more information about therapeutic equivalence will "serve state health agencies in the administration of their drug product selection laws" is in accord with ASHP's position on this important issue.

However, while ASHP agrees with the rationale behind the issuance of the guidance document, we are not convinced that the FDA has fully considered the safety implications of allowing prescription drug manufacturers to place therapeutic equivalence codes on already-cluttered drug labels.

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In statements that ASHP made at the FDA's FDAMA Sec. 406(b) stakeholders meetings in August and September 1998, we pointed out that poor product design -- including poor label readability, poor nomenclature, look-alike and sound-alike product names, and confusing abbreviations -- was a contributing factor in many medication errors. We noted that patients are being harmed because of these poor designs. We suggested that the agency should require that product-design elements undergo formal failure mode and effects analysis as part of the drug application process.

The agency's inaction in adequately dealing with the potential of drug products' packaging and labeling to induce errors continues to put patients at risk, and implementing the guidance document on placing therapeutic equivalence codes on prescription drug labels without an adequate analysis to satisfy safety and medication error concerns would, in ASHP's opinion, be a step backward on the part of the FDA. The agency should move forward with its good intentions of providing health professionals and consumers with important and useful information, but reevaluate its proposed method of providing that information. Better ways of providing therapeutic equivalence information could be by placing that information in a product's professional labeling (package inserts), and on the agency's web site.

ASHP appreciates the opportunity to comment on this significant effort by the FDA to advise the public on the therapeutic equivalence or inequivalence of approved prescription drugs. Feel free to contact me if you have any questions regarding our comments.

Sincerely,

Gary C. Stein, Ph.D.
Director, Federal Regulatory Affairs

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